K092192

FEB 12 2010

FHC

Microelectrodes and Instrumentation for Neuroscience Research and Clinical microTargeting™

FHC Corporate & Manufacturing
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510(k) SUMMARY

(Per 807.92 510(k) content instructions)

A. Summary

(1) Submitter's name, address, telephone number, a contact person and date summary was prepared:

FHC, Inc.
1201 Main Street
Bowdoin, Maine 04287
Tel: 207-666-5651
Fax: 207-666-8539
Contact: Lee D. Margolin, MS, PhD.
January 12, 2010

(2) Name(s) of device:

Proprietary/Trade Name:	WayPoint™ Stereotactic System
Common Name:	Stereotaxic instrument
Classification Name:	Stereotaxic instrument (21 CFR 882.4560) Product Code (84 HAW)

(3) Legally Marketed Predicate Devices to which submitter claims substantial equivalence:

The WayPoint™ Stereotactic System functionality is claimed to be substantially equivalent to the following:

1. FHC, Inc. microTargeting™ Drive System (K003776; decision date: February 23, 2001; product code HAW).
2. Howmedica Leibinger, Inc. Ost-Reg Marker System (K961120; decision date: May 10, 1996; product code HAW).
3. Elekta Instruments AB Leksell SurgiPlan (K080250; decision date: May 13, 2008; product code HAW).
4. Elekta Instruments AB Leksell Stereotactic System (K972324; decision date: March 2, 1998; product code HAW).

(4) Description of device:

The WayPoint™ Stereotactic System, (WPS System) accurately locates and rigidly supports neurosurgical or other surgical instruments relative to specific anatomical structures or targets, thus facilitating microelectrode recording, stimulation, data collection, device implantation and other surgical procedures. The WPS System provides patient-customized stereotactic fixtures designed to be secured on skull-based anchor mounting sets to hold and

align surgical instruments with patient anatomy and to allow selected targets to be reached with sub-millimeter accuracy. The WPS System consists of several components that work together to become a stereotactic system. These components are:

1) the WayPoint™ Stereotactic Anchor System;
2) the WayPoint™ Stereotactic Platform Adapter;
3) Device mounting hardware for the Platform; and,
4) WayPoint™ compatible Planning software such as:
   a. WayPoint™ Planner; or,
   b. VoXim® Planning software.

The WayPoint™ Stereotactic Anchor/Locator System provides tools and components for the temporary implantation of anchors to be used as reference points and mounting sets for the surgical procedure. The WPS System software designs a Stereotactic Platform Adapter that will mount to the WayPoint™ Stereotactic Anchor System. For each surgical instrument or device to be mounted to the Stereotactic Platform Adapter, suitable hardware is provided to act as a secure interface and allow flexibility in targeting, if required. The two existing software components of the WPS System (WayPoint™ Planner and VoXim® microTargeting™ Planning software) provide tools to create a Stereotactic Platform Adapter from scanned patient images.

(5) Statement of intended use:

The WayPoint™ Stereotactic System is intended to be used with commercially available stereotactic systems for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, implantable electrodes or other instruments in the brain or nervous system.

(6) Comparison of Technological Characteristics to Predicate Devices:

The WayPoint™ Stereotactic System is substantially equivalent to the predicate devices in design, construction, materials, intended use and performance characteristics. No new issues of safety or effectiveness are introduced in the use of this device.

B. Performance data

Both phantom- and imaging-based studies were conducted in order to evaluate the accuracy of the WPS System. Results from the phantom-based study showed that the Stereotactic Platform Adapter produced by the WPS System is accurate to a submillimetric level. Using the WPS System, a comparison of intraoperative stereotactic coordinates of an implant to its position in postoperative CT images demonstrated accuracies comparable to those of conventional frames. Finally, in a study that compared preoperative target selection and final placement verification based on CT images, error measurements were comparable to those for the same procedure as described by other groups using a standard stereotactic frame.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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FHC, Inc.
c/o Lee D. Margolin, M.S., Ph.D.
Director of Research and Compliance
Quality System Officer
1201 Main Street
Bowdoin, ME 04287-7302

Re: K092192
Trade/Device Name: WayPoint™ Stereotactic System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: January 15, 2010
Received: January 19, 2010

Dear Dr. Margolin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

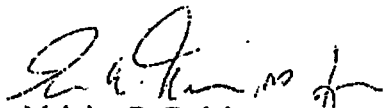
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092192

Device Name: WayPoint™ Stereotactic System

Indications for Use:

The WayPoint™ Stereotactic System is intended to be used with commercially available stereotactic systems for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, or other instruments in the brain or nervous system.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K092192